IN THE CLAIMS

Kindly replace claims 6, 10, 28 and 29 by the following claims.

C1

6 (twice amended). A Method according to claim 28, which is characterised in that the nanodispersion comprises as component

(a) a phospholipid, a hydrated or partially hydrated phospholipid, a lysophospholipid, or mixtures thereof.

C2

10 (twice amended). A Method according to claim 28, which is characterised in that the nanodispersion comprises as component (b)

polyethoxylated sorbitan fatty acid esters, polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides and polyethoxylated carbohydrates.

C3

28 (twice amended). A method of preparing a pharmaceutical formulation of a lipophilic pharmaceutical active agent in the form of an aqueous nanodispersion, which steps consist essentially of

(α) mixing the components

(a) 0.1 to 30 % by weight of a phospholipid,

(b) 1 to 50 % by weight of a polyoxyethylene coemulsifier,

(c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C_4-C_{18}triglyceride, and a lipophilic pharmaceutical active agent, in which any pharmaceutically active agent is lipophilic and is always present as component (c), and

(d) 0.63 to 14.2 % by weight of ethanol

in conventional stirring apparatus until a homogeneous clear liquid is obtained and

(β) adding the liquid obtained in step (α) to a water phase, wherein (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.

29 (twice amended). An aqueous nanodispersion of a lipophilic pharmaceutical active agent, which consists essentially of

(a) 0.1 to 30 % by weight of a phospholipid,

C 3 cont'd

(b) 1 to 50 % by weight of a polyoxyethylene coemulsifier,

(c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C_4-C_{18}triglyceride, and a lipophilic pharmaceutical active agent, in which any pharmaceutically active agent is lipophilic and is always present as component (c), and

(d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight, plus

(e) a water phase,

which formulation is obtainable by

(α) mixing the components (a), (b), (c), and (d) until a homogeneous clear liquid is obtained, and

(β) adding the liquid obtained in step (α) to the water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces, and whereby the particles in the nanodispersion have an average diameter <50 nm.

STATUS OF THE CLAIMS

Claims 2, 6, 10, 15-21, 24 and 28-29 were pending in this application.

Claims 2, 6, 10, 15-21, 24 and 28-29 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Weder, U.S. Patent 5,997,888 in view of WO 96/37192.

Claims 6, 10, 28 and 29 have been amended.

Claims 2, 6, 10, 15-21, 24 and 28-29 are presented for reconsideration.

REMARKS

Claims 6, 10, 28 and 29 have been amended by replacement. No other claims have been amended. No claims have been added.

Another version of the amended claims, showing the changes relative to the previous version, is appended. Additions are shown by underlining. Deletions are shown by strikethrough rather than bracketing since the claims may contain bracketing that is to remain. No new matter has been added.